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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,757	03/29/2004	Hsiang Wang	39524.9800	2850

7590 12/23/2005

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EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,757	WANG ET AL.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 8-26 is/are pending in the application.
- 4a) Of the above claim(s) 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment of October 13, 2005 is hereby acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected Group I in the reply filed on June 10, 2005.

Claims 22-26 are withdrawn from further consideration.

Claims Pending

Applicant has cancelled claims 1-7. Claims 8-21 will be examined on the merits.

Claim Objections

Duplicate Claims Warning

The objection to duplicate claims warning has been withdrawn in view of Applicant's cancellation of claims 1-7.

Claim Rejections - 35 USC § 112

The claim rejection under 35 USC § 112, second paragraph, has been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

Claims 1, 7-8, 16-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuok *et al.* (US 6,790,464 B2) as stated previously in the prior Office action.

Kuok *et al.* (US 6,790,464 B2) teach a composition that contains *Fructus cnidii* and *Semen cuscutae* which can be extracted with an alcohol extract such as ethanol. The composition can be incorporated into any means of administration such as liquid, tablet powder, capsule or by injection (column 7, lines 6, 16-17; column 10, lines 28-31, 53-55, 59-61; column 16, 66-67; column 17, lines 1, 24-35; claim 2).

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Applicant's arguments filed October 13, 2005 have been fully considered but they are not persuasive.

In response to **Applicant's argument** that osteoporosis and prostate disorders are irrelevant to one another. This is not is persuasive because the composition in Kuok *et al.* is structurally the same as the claimed composition. Thus, the two compositions are the same. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that Kuok *et al.* does not teach or suggest a mixed extract of *Fructus cnidii* and *Semen cuscutae* in an amount sufficient to treat osteoporosis. This not found persuasive because as discussed above the composition in Kuok *et al.* is structurally the same as the claimed composition. Thus, the two compositions are the same. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

Therefore, the rejection is deemed proper and is maintained.

Claim Rejections - 35 USC § 103

Claims 8-13, 16-18 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kuok *et al.* (US 6,790,464 B2) as stated previously in the prior Office action.

Kuok *et al.* (US 6,790,464 B2) disclose a composition for the treatment of prostate disorders and prostatic carcinoma which contains *Fructus cnidii* and *Semen cuscutae* which can be extracted with an alcohol extract such as ethanol. The composition can include various additional ingredients such as minerals (i.e. calcium) and can be incorporated into any means of administration such as liquid, tablet powder, capsule or by injection (column 7, lines 6, 16-17; column 9, lines 58-60; column 10, lines 28-31, 53-55, 59-61; column 16, 66-67; column 17, lines 1, 24-35).

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Applicant's arguments filed October 13, 2005 have been fully considered but they are not persuasive.

Applicant argues a pharmaceutical composition should be defined by a composition together with the disease it treats and should be inseparably considered. This is not found persuasive because a composition claimed is not considered for its intended use. A composition is composition regardless of its intended use. The composition is structurally the same as the claimed invention thus a recitation of intended use must be structurally different to distinguish the claimed invention from the prior art.

In response to **Applicant's argument** that Kuok *et al.* fail to show anything about osteoporosis or the connection between the composition and osteoporosis. This is not is persuasive because the composition in Kuok *et al.* is structurally the same as the claimed composition. Thus, the two compositions are the same. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In response to **Applicant's argument** that Kuok *et al.* is nonanalogous art, it has been held that a prior art reference must either be in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the Applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Applicant's invention claimed is in the same field as Kuok *et al.* meaning that both Kuok *et al.* and the claimed invention has a pharmaceutical composition in treating a disease. As discuss *supra*, the composition in Kuok *et al.* are structurally the same as the claimed composition. Thus, the two compositions are the same. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

Therefore, the rejection is deemed proper and is maintained.

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Claims 14-15 and 19-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kuok *et al.* (US 6,790,464 B2) as applied to claims 1-13, 16-18 and 21 above, and further in view of Baron (US 2004/0071789) as stated previously in the prior Office action.

Kuok *et al.* (US 6,790,464 B2) disclose a composition for the treatment of prostate disorders and prostatic carcinoma, which contains *Fructus cnidii* and *Semen cuscutae*, which can be extracted with an alcohol extract such as ethanol. The composition can include various additional ingredients such as minerals (i.e. calcium) and can be incorporated into any means of administration such as liquid, tablet powder, capsule or by injection (column 7, lines 6, 16-17; column 9, lines 58-60; column 10, lines 28-31, 53-55, 59-61; column 16, 66-67; column 17, lines 1, 24-35). Kuok *et al.* does not disclose the specific calcium-containing substances or vitamin D₃.

Baron (US 2004/0071789) discloses a composition of administering calcium (i.e. calcium carbonate or calcium phosphate) and vitamin D can be added to the composition to reduce the risk of prostate carcinoma ([0010], [0014], [0068] and [0071]).

Applicant's arguments filed October 13, 2005 have been fully considered but they are not persuasive. The reasons are discussed *supra*.

Therefore, the rejection is deemed proper and is maintained.

Summary

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Terry McKelvey, can be reached on (571) 272-0775. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe

12-15-05

**SUSAN COE
PRIMARY EXAMINER**